MAXIMUS Federal Services

Case Number:	CM15-0093987		
Date Assigned:	05/26/2015	Date of Injury:	05/23/2006
Decision Date:	07/16/2015	UR Denial Date:	04/24/2015
Priority:	Standard	Application Received:	05/15/2015

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
State(s) of Licensure: Pennsylvania
Certification(s)/Specialty: Internal Medicine

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 47 year old male who sustained an industrial injury on 05/23/2006. He reported injuring his lower back, chest, and right shoulder while cutting wood while standing on a ladder. The injured worker is currently temporarily totally disabled. The injured worker is currently diagnosed as having chronic low back pain with bilateral lower extremity radicular symptoms, depression and anxiety, insomnia, and erectile dysfunction. Treatment and diagnostics to date has included electrodiagnostic study, epidural injections, chiropractic treatment, lumbar spine MRI which showed disc desiccation and protrusion, functional capacity evaluation, psychotherapy, and medications. Tramadol was prescribed since October 2011. Multiple reports note that the injured worker denied diabetes or hypertension. Work status was noted as temporarily totally disabled. In a progress note dated 03/19/2015, the injured worker presented with complaints of trouble sleeping due to pain, difficulty with sexual functioning, and back pain. Objective findings include the injured worker appearing a little anxious, with clear lungs, regular heart rate and rhythm, and benign abdomen. The treating physician reported requesting authorization for Tramadol, Cialis, and multiple laboratory tests. on 4/24/15, Utilization Review non-certified or modified requests for the items currently under Independent Medical Review.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

Uknown prescription of Tramadol: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 74-96.

Decision rationale: Tramadol (ultram) is a centrally acting synthetic opioid analgesic which is not recommended as a first line oral analgesic. Multiple side effects have been reported including increased risk of seizure especially in patients taking selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs) and other opioids. It may also produce life-threatening serotonin syndrome. Opioids have been prescribed since 2007. Reports from October 2011 to the present note use of tramadol. There is insufficient evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, and opioid contract. None of these aspects of prescribing are in evidence. One urine drug screen was mentioned in March 2015 without submission of results. Per the MTUS, opioids are minimally indicated, if at all, for chronic non-specific pain, osteoarthritis, "mechanical and compressive etiologies," and chronic back pain. There is no evidence of significant pain relief or increased function from the opioids used to date. The MTUS states that a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. There is no evidence that the treating physician has utilized a treatment plan NOT using opioids, and that the patient "has failed a trial of non-opioid analgesics." Ongoing management should reflect four domains of monitoring, including analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors. The documentation does not reflect improvement in pain. Change in activities of daily living, discussion of adverse side effects, and screening for aberrant drug-taking behaviors were not documented. The MTUS recommends urine drug screens for patients with poor pain control and to help manage patients at risk of abuse. There is no record of a urine drug screen program performed according to quality criteria in the MTUS and other guidelines. The requested prescription is for an unstated quantity, and the medical records do not clearly establish the quantity. Requests for unspecified quantities of medications are not medically necessary, as the quantity may potentially be excessive and in use for longer than recommended. As currently prescribed, tramadol does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary.

Cialis 20mg #6 with 2 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Guidelines on male sexual dysfunction; Wespes E, Eardley I, Giuliano F. Arnhem (The Netherlands): European Association of Urology, 2013 Mar. p.54.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate: Tadalafil: drug information. In UpToDate,

edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015. UpToDate, Evaluation of male sexual dysfunction. In UpToDate, edited by Ted W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: This injured worker has a diagnosis of erectile dysfunction. The MTUS and ODG are silent with regards to Cialis. Cialis (tadalafil) is a phosphodiesterase inhibitor indicated for the treatment of erectile dysfunction (ED) and benign prostatic hypertrophy (BPH). For treatment of erectile dysfunction, the usual dose is 10 or 20 milligrams at least 30 minutes prior to anticipated sexual activity as one single dose and not more than once daily, or 2.5 mg once daily at the same time daily without regard to timing of sexual activity. Cialis is contraindicated with concurrent use of nitrates. According to the UpToDate reference cited above, there are multiple possible causes for erectile dysfunction. Causes may be behavioral or organic. There may be important medical conditions causing erectile dysfunction in some patients. Some of the possible causes are androgen deficiency, depression, prescription and recreational drugs, inadequate arterial blood flow into (failure to fill) or accelerated venous drainage out of (failure to store) the corpora cavernosae, prior prostate surgery, antidepressant medication, unresolved patient/partner conflict. The evaluation begins with a sexual history and physical examination. A careful history and physical examination is necessary to evaluate erectile dysfunction. Laboratory testing may be required for some patients. The cited reference provides detailed recommendations for evaluation and treatment of erectile dysfunction. In this case, the treating physician has not provided evidence of a sufficient clinical evaluation of erectile dysfunction. The causation is not clear from the medical reports, and a phosphodiesterase-5 inhibitor may or may not be the best treatment for the condition present in this patient. Cialis is not medically necessary based on the lack of sufficient evaluation or indications per the available records and medical evidence.

1 comp metabolic panel without GFR: Overturned

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate: evaluation of male sexual dysfunction. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: This injured worker was noted to have erectile dysfunction and decreased libido. Appropriate laboratory tests for men with sexual dysfunction typically include fasting glucose or hemoglobin A1C to examine for diabetes, complete blood count, comprehensive metabolic profile to assess liver and kidney function, thyroid stimulating hormone (TSH) to rule out thyroid disease, lipid profile to assess cardiac risk factors, and serum total testosterone to assess gonadal function. The Utilization Review determination denied the request for comprehensive metabolic panel, stating that there was no assessment, rationale, or diagnosis which would lead the clinical reviewer to deem the request warranted. The Utilization Review determination did not take into consideration the diagnosis of erectile dysfunction. As a complete metabolic panel is part of the appropriate testing for men with sexual dysfunction, the request for 1 comp metabolic panel without GFR is medically necessary.

1 fasting lipid panel: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Michigan Quality Improvement Consortium. Screening and management of hypercholesterolemia. 2013 Aug. 1 p.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Rosenson, Robert S. et al, Measurement of blood lipids and lipoproteints, in UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015. UpToDate: evaluation of male sexual dysfunction. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: The MTUS and ODG are silent with regard to lipid testing in the absence of statin therapy. A fasting lipid profile is recommended when screening for lipid abnormalities and when monitoring therapy, with monitoring performed every 6 to 12 months. This injured worker was noted to have erectile dysfunction and decreased libido. Appropriate laboratory tests for men with sexual dysfunction typically include fasting glucose or hemoglobin A1C to examine for diabetes, complete blood count, comprehensive metabolic profile to assess liver and kidney function, thyroid stimulating hormone (TSH) to rule out thyroid disease, lipid profile to assess cardiac risk factors, and serum total testosterone to assess gonadal function. The Utilization Review determination denied the request for comprehensive metabolic panel, citing the lack of clinical findings to support the necessity of this laboratory test. The Utilization Review determination did not take into consideration the diagnosis of erectile dysfunction. As a lipid profile is part of the appropriate testing for men with sexual dysfunction, the request for 1 fasting lipid panel is medically necessary.

C-reactive protein and HS CRP: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medical Services Commission. Rheumatoid arthritis; diagnosis, management and monitoring. British Columbia Medical Services Commission, 2012 Sep 30. p.7.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate: acute phase reactants. In UpToDate, Post TW (Ed), UpToDate, Waltham, MA 2015.

Decision rationale: Elevations in the c-reactive protein (CRP) occur in association with acute and chronic inflammation due to a range of causes, including infectious diseases and noninfectious inflammatory disorders. Assessment of acute phase reactants (such as CRP or erythrocyte sedimentation rate (ESR) may be helpful in certain conditions, such as rheumatoid arthritis, polymyalgia rheumatica, giant cell arteritis, systemic lupus erythematousus, cardiovascular disease, infection, and malignancy. In this case, there was no documentation of any of these conditions for this injured worker. The treating physician has not provided a reason for the request for a c-reactive protein level. Tests should not be performed without specific

indications. Due to lack of specific indication, the request for C-reactive protein and HS CRP is not medically necessary.

Hemoglobin A1c: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Diagnosis and management of type 2 diabetes mellitus in adults. Institute for Clinical Systems Improvement. Riethof M, Flavin PL, Lindvall B, Michels R, O'Connor P, Redmon P, Retzer K. 2012 Apr. 141 p.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG diabetes chapter: glucose monitoring. UpToDate: evaluation of male sexual dysfunction. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: The ODG recommends self monitoring of blood glucose for people with type 1 diabetes and those with type 2 diabetes who use insulin therapy. Hemoglobin A1C should be measured at least twice yearly in all patients with diabetes and at least 4 times a year in patients not at target. This injured worker did not have a diagnosis of diabetes; however, he was noted to have erectile dysfunction and decreased libido. Appropriate laboratory tests for men with sexual dysfunction typically include fasting glucose or hemoglobin A1C to examine for diabetes, complete blood count, comprehensive metabolic profile to assess liver and kidney function, thyroid stimulating hormone (TSH) to rule out thyroid disease, lipid profile to assess cardiac risk factors, and serum total testosterone to assess gonadal function. The Utilization Review determination denied the request for comprehensive metabolic panel, citing the lack of diagnosis of diabetes. The Utilization Review determination did not take into consideration the diagnosis of erectile dysfunction. As a Hemoglobin A1c is part of the appropriate testing for men with sexual dysfunction, the request for Hemoglobin A1c is medically necessary.

Iron (Total), serum magnesium: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Approach to the adult patient with anemia. Causes of hypomagensemia. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: The treating physician has not provided a reason for the request for iron and magnesium levels. There was no documentation of anemia, iron deficiency, iron overload states, or abnormal level of magnesium. There was no discussion of conditions noted to cause alterations in magnesium levels, such as renal issues, or use of medications which affect magnesium levels. Tests should not be performed without specific indications. Due to lack of specific indication, the request for Iron (Total), serum magnesium is not medically necessary.

1 PSA: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Guideline Clearinghouse. Screening for prostate cancer. 1998 Dec. (Revised 2014 Mar).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate: measurement of prostate specific antigen. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: Serum prostate specific antigen (PSA) is a marker for prostate cancer. Its sensitivity and specificity are not perfect as a screening tool. Causes of an elevated serum PSA include benign prostatic hypertrophy, prostate cancer, prostate inflammation and infection, perineal trauma, and sexual activity. There was no discussion of any of these conditions for this injured worker. The treating physician has not provided a reason for the request for PSA. Tests should not be performed without specific indications. Due to lack of specific indication, the request for PSA is not medically necessary.

Erythrocyte sedimentation rate (ESR): Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.*CharFormat

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 207-209.

Decision rationale: Per the MTUS, an erythrocyte sedimentation rate, complete blood count, and tests for autoimmune diseases (such as rheumatoid factor) can be useful to screen for inflammatory or autoimmune sources of joint pain. Assessment of acute phase reactants (such as CRP or erythrocyte sedimentation rate (ESR) may be helpful in certain conditions, such as rheumatoid arthritis, polymyalgia rheumatica, giant cell arteritis, systemic lupus erythematousus, cardiovascular disease, infection, and malignancy. In this case, there was no documentation of any of these conditions for this injured worker. The treating physician has not provided a reason for the request for an erythrocyte sedimentation rate (ESR). Tests should not be performed without specific indications. Due to lack of specific indication, the request for Erythrocyte sedimentation rate (ESR)is not medically necessary.

TSH, T3 uptake and T4 (thyroxine) total: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medical Services Commission. Thyroid function tests: diagnoses and monitoring of thyroid function disorders in adults. British Columbia Medical Services Commission, 2010 Jan. 6 p.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Ross, Douglas et al, Laboratory assessment of thyroid

function, in UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015. UpToDate: evaluation of male sexual dysfunction. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: Screening in patients at risk of having thyroid disease should begin with measurement of the serum thyroid stimulating hormone (TSH). Measurement of serum free thyroxine is indicated when drugs or illness may alter the concentration of binding proteins with T4 and the free and total hormone concentrations may not be concordant, when the TSH is abnormal, when pituitary or hypothalamic disease is suspected, and when the patient has convincing symptoms of hyper- or hypothyroidism despite a normal TSH result. Measurement of serum free triiodothyronine (T3) is indicated when drugs or illness may alter the concentration of binding proteins with T3 and the free and total hormone concentrations may not be concordant, and when the TSH is low, to determine the degree of hyperthyroidism. This injured worker was noted to have erectile dysfunction and decreased libido. Appropriate laboratory tests for men with sexual dysfunction typically include fasting glucose or hemoglobin A1C to examine for diabetes, complete blood count, comprehensive metabolic profile to assess liver and kidney function, thyroid stimulating hormone (TSH) to rule out thyroid disease, lipid profile to assess cardiac risk factors, and serum total testosterone to assess gonadal function. Per the citation, screening for thyroid disease should begin with a TSH, and the TSH (but not T3 uptake and T4) are indicated as part of the evaluation for sexual dysfunction. If the TSH were found to be abnormal, further testing would be indicated. As the T3 uptake and T4 (thyroxine) total are not indicated for screening for thyroid dysfunction in the setting of erectile dysfunction, the request for TSH, T3 uptake and T4 (thyroxine) total is not medically necessary.

Urinalysis complete with reflex culture: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation University of Michigan Health System. Urinary tract infection. 2011 Jun. 8 p.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate: Wald, Ron: Urinalysis in the diagnosis of kidney disease. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: The urinalysis is used in evaluating acute and chronic kidney disease, and can be used to monitor the course of kidney diseases in some patients. It may be used in patients with suspected kidney disease (on the basis of clinical findings or concurrent illness), urinary tract infection, or kidney stones. In this case, there was no documentation of presence of suspicion of kidney disease, urinary tract infection, or kidney stones. No urinary signs or symptoms were discussed. The treating physician has not provided a reason for the request for a Urinalysis complete with reflex culture. Tests should not be performed without specific indications. Due to lack of specific indication, the request for Urinalysis complete with reflex culture is not medically necessary.

1 serum uric acid: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Spanish Society of Rheumatology (SER). Clinical practice guidelines for management of gout. 2013. 161 p.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Uric acid balance. Clinical manifestations and diagnosis of gout. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: Decreased efficiency of renal uric acid excretion is responsible for most cases of hyperuricemia. Hypouricemia may be caused by decreased production (primarily due to rare enzyme defects) or to increased urinary excretion. Hyperuricemia may lead to gout and nephrolithiasis. In this case, there was no documentation of hyper or hypoureicemia, gout, or kidney stones. The treating physician has not provided a reason for the request for measurement of uric acid. Tests should not be performed without specific indications. Due to lack of specific indication, the request for 1 serum uric acid is not medically necessary.

Vitamin D, liquid chromatography/mass spec: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation U.S. Preventive Services Task Force. Screening for vitamin D deficiency in adults. 2015 Jan 20. 133-140.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter: vitamin D and Other Medical Treatment Guidelines UpToDate: Vitamin D deficiency in adults: Definition, clinical manifestations, and treatment. In UpToDate, edited by Ted W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: The ODG states that vitamin D is not recommended for the treatment of chronic pain. Vitamin D supplementation is indicated for a documented vitamin deficiency. The UpToDate citation states that normal risk adults do not need assessment, but that it is appropriate to measure vitamin D level in individuals who are in high risk groups. Groups at high risk for vitamin D deficiency include those who are dark skinned, obese, taking medications that accelerate the metabolism of Vitamin D, hospitalized or institutionalized, and those with limited effective sun exposure, osteoporosis, or malabsorption. In high risk adults, follow up vitamin D measurements should be made approximately three to four months after initiating maintenance therapy to confirm that the target level has been achieved. In this case, there was no documentation of high risk for vitamin D deficiency for this injured worker. The treating physician has not provided a reason for the request Vitamin D, liquid chromatography/mass spec. Tests should not be performed without specific indications. Due to lack of specific indication, the request for Vitamin D, liquid chromatography/mass spec is not medically necessary.